REMARKS

In the Office Action dated February 8, 2008, claims 14-27 were withdrawn from further consideration in the instant application. The Information Disclosure Statement was acknowledged and it was noted that the specification lacks section headings. A correction was required. Claims 1-13 were provisionally rejected on the ground of non-statutory obviousness type double patenting as being unpatentable over claims 1-13 of co-pending application Serial No. 10/549,211. Claims 1-11 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. 2002/0179166 to Houston et al. (Houston). Claim 12 was rejected under 35 U.S.C. § 103 as being unpatentable over Houston. Claim 13 was also rejected under 35 U.S.C. § 103 as being unpatentable over Houston in view of U.S. Patent No. 5,670,161 to Healy.

Status of the Claims

Applicant takes this opportunity to cancel the withdrawn claims, claims 14-27, without prejudice to their reintroduction in a divisional application.

In addition, applicant has cancelled claims 4-7 similarly without prejudice.

Information Disclosure Statement

It was noted in the Office Action that the Information Disclosure Statement filed on December 6, 2005 fails to comply with 37 C.F.R. 1.98(a)(3) because it does not include a concise explanation of the relevance of one particular patent document, namely, Document AS, FR 2,666,502. However, applicant notes that in the relevant Information Disclosure Statement on page 2 is a description of Document AS, namely,:

"....the French '502 publication pertains to a synthetic vascular graft, including a main tube and a pair of tubes 6 and 7 protruding away from the main tube at an angle A, as is evident from Figure 1."

Therefore, it is respectfully submitted that Document AS should be considered by the Examiner.

Specification

In light of paragraphs 3 and 4 of the Office Action, applicant has attended to adding section headings to the specification. Therefore, it is believed that this objection has been overcome.

Double Patenting

Claims 1-13 were provisionally rejected over claims 1-13 of co-pending application Serial No. 10/549,211. However, this rejection was only provisional because the conflicting claims have not in fact been patented. If and when they are, then a terminal disclaimer will be considered. At this point, the claims of the '211 application have not yet been examined. Therefore, this rejection is premature.

Independent Claim 1 and Dependent Claims 2, 8-13 and 32

Independent claim 1 and its dependent claims 2 and 8-13 were rejected as being anticipated by Houston. It was stated that Houston discloses a graft comprising flow tubing having a tube in portion 3 defining a flow lumen. It was also asserted that

paragraph 56 describes that the flow lumen of the tubing portion is substantially free of ribs or grooves. Paragraph 56 refers to the embodiment of Figures 7a and 7b. There, it is stated that "the flow guidance forming patterns [of Figure 7] may be an integral component of the conduit."

However, Figures 7a and 7b and paragraph 56 fail to disclose a graft which has a center line following a helical path. This is a recitation of claim 1, and is not seen in the embodiment discussed in paragraph 56. Rather, Figure 7b shows helical wires 13a, 13b, 13c which are symmetrically distributed about the circumference of the conduit 400. If one considers the locus of the centroids of successive tube cross sections along the length of the tube, this locus is a straight line. Thus, these wires are twisted about an axis which is straight. Therefore, it is respectfully submitted that independent claim 1, which recites "wherein the centerline of the flow lumen follows a substantially helical path" patentably defines over the subject matter discussed in paragraph 56 of the Houston reference and the embodiment of Figures 7a and 7b discussed therein.

The Office Action also notes Figures 1-4b of Houston. Dealing first with Figure 1, this figure discloses a helical structure 100 comprising ribs 1a - 1c. These are disposed in a helical flow guiding formation along the longitudinal axis of the structure 100. However, Figure 1 fails to disclose a graft at all. Paragraph 47 of Houston notes that the helical structure 100 is meant to be fitted over a graft 3 as shown generally at 200 in Figure 2. Applicants note that Figure 2, as well as Figures 3, 4a and 4b, all disclose tubes with various non circular cross sections. Importantly, the cross sectional shape has been twisted along a straight axis. This can be most clearly seen in Figure 4b where the cross sectional shape is shown to be approximately triangular. This is discussed in paragraph 50 of Houston. The cross sections at two points along the

length of the graft in Figure 4a is labeled with the numerals 9 and 10 in Figure 4b.

It should be appreciated that the centroids of the cross sections 9 and 10 are coincident in the end view of Figure 4b. Thus, the locus for these centroids, i.e., the center line of the tube is a straight line. Therefore, the embodiment of Houston in Figures 4a and 4b fails to disclose a graft where the center line of the tubing follows a substantially helical path. This is in contrast with the recitation in claim 1 as previously noted. Figures 2 and 3 of Houston show a similar construction in that a non circular cross section of the tube is twisted about a straight axis. In sum, none of the mentioned figures in Houston disclose or teach a tube with a center line that follows a substantially helical path. Therefore, claim 1 patentably defines over Houston as proposed in the Office Action.

Applicant notes the embodiment of Figure 5 in Houston. However, this figure of Houston is already discussed in the present application in relation to the equivalent international publication, WO 02/98325. This discussion can be found on page 3, at lines 19-22 of the instant application. It is there mentioned that there is no "line of sight" along the inside of the tubing, i.e., along the lumen of the graft.

In summary, Houston does not anticipate independent claim 1. Therefore, it also does not anticipate dependent claims 2 and 8-13.

Moreover, claim 1 is also not rendered unpatentable under 35 U.S.C. § 103(a) by Houston. As previously noted, the tubing portions disclosed in Houston (with the exception of Figure 5) attempt to induce swirl flow through the use of internal grooving or ridging. However, the use of ribs or grooves in an otherwise cylindrical tube or the use of a non-circular section which twists along the length of the tube may not reliably

induce swirl flow across the entire cross section of the flow. As discussed in the instant specification, there may be a tendency for the flow nearer to the center of the tube to follow a linear path, particularly for flows at higher Reynolds numbers (see page 2, lines 26-34).

Therefore, the tubes with grooving or ridging or twisted tubes of a non circular cross section, such as the designs shown in Houston, suffer from the disadvantage that there can be linear flow near the center of the tube. This leads to reduced mixing and mass transport across the cross section of the tube, as noted in the instant specification (page 10, lines 10-22).

In contrast, with a tubing portion wherein the center line of the flow lumen follows a substantially helical path, as recited in claim 1, the mixing over the cross section of the entire tube is promoted. As a result, there is a reduction in the likelihood of regions of stagnation (see the instant specification, page 10, lines 2-9). For a fluid traveling along the graft recited in claim 1, the fluid will generally have a swirl component due to the low amplitude of the helical center line of the graft, even though it could potentially follow a straight path (see the instant specification, page 5, lines 21-24).

In sum, it would not have been obvious to modify the various tube designs shown in Houston, which show grooving or ridging imparted on an otherwise circular tube, or a non-circular twisted arrangement, to become a graft of the type recited in claim 1. The reason for this is because the advantages of the claimed graft, namely, a graft having a tubing portion with a helical center line having an amplitude less than or equal to about one half the internal diameter of the tubing portion, are in no way recognized by Houston.

Dependent claims 2 and 7-13 merely further patentably define the detailed subject matter of their parent claim. As such, these claims are also believed to be in condition for allowance over Houston, as well as the remainder of the cited art.

Applicant takes this opportunity to add new dependent claim 32. This claim recites that the tubing portion comprises a tubular wall which resists reduction of the amplitude of the helical center line. Support for this claim can be found in the instant specification at page 11, lines 26-28. It was also recited in original claim 4. No such teaching or disclosure can be found in Houston. Therefore, this claim is also patentable over the Houston reference, as well as the remainder of the cited art.

Independent Claim 3 and Dependent Claims 28-31 and 33

Independent claim 3 was also rejected as being anticipated by Houston. As with claim 1, claim 3 recites that the center line of the flow lumen follows a substantially helical path, with a helix angle less than or equal to 45 degrees. Claim 3 also recites that the amplitude of the helical center line divided by the internal diameter of the tubing portion is at least 0.05. For the same reasons as advanced above with regard to claim 1, it is respectfully submitted that claim 3 patentably defines over Houston.

Applicant takes this opportunity to add dependent claims 28-31 and 33. Claim 28 recites that the helix angle is less than or equal to 15 degrees. This recitation can also be found in currently pending claim 8.

Claim 29 is similar to pending claim 9. Claim 30 is similar to pending claim 12 and claim 31 is similar to pending claim 13. As a result, all of these claims are believed to patentably define over Houston, as well as the remainder of the cited art for the

reasons advanced above.

Finally, claim 33 is similar to claim 32. As noted above, the subject matter of this claim patentably defines over Houston and is supported by the instant specification.

French Document

During the prosecution of the European application, a new prior art document was cited. It is French Patent Publication 2 248 015. A copy of this document is enclosed in a Supplemental Information Disclosure Statement submitted herewith. Also enclosed is a machine translation of this French document.

In the French '015 document, there is described a helical graft designed to resist kinking, as is shown in Figure 3. It is apparent that as the helical angle reduces, the anti-kinking properties of the tube are also reduced. At the limit of the helix angle reducing to zero, the helical tube becomes a normal – non-helical – tube. It will then have lost all its anti-kinking properties. Thus, the French document does not provide any reason to reduce the helix angle of its tube below that disclosed in the document, since to do so would to go against the explicit teaching in French '015. Applicant has calculated the helix angle to be approximately 54 degrees.

In this regard, applicant notes that the two independent claims, claims 1 and 3, recite that the graft tubing has a substantially helical path, which has a helix angle of less than 45 degrees. Therefore, both independent claims 1 and 3 patentably define over the French '015 patent.

Applicant notes that such a claim limitation has been accepted as being both novel and inventive by the European Examiner.

In view of the foregoing, it is respectfully submitted that the pending claims, namely, independent claim 1 and its dependent claims 2, 8-13 and 32 and independent claim 3 and its dependent claims 28-31 and 33 are in condition for allowance. Such allowance is earnestly solicited.

Respectfully submitted,

FAY, SHARPE, FAGAN,
MINNICH & McKEE, LLP

7 May 2008
Date

Jay F. Moldovanyi
Reg. No. 29,678
1100 Superior Avenue, 7th Floor
Cleveland, Ohio 44114-2579
(216) 861-5582

N:\DEHN\200008\KAN0009853V001.docx